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Morgan & Finnegan
3 World Financial Center
New York, NY 10281-2101

EXAMINER	
COTTON, ABIGAIL MANDA	

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1617	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/505,299	WAUGH ET AL.	
	Examiner	Art Unit	
	Abigail M. Cotton	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *8/20/04,7/7/05*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-34 and 36-43* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-34 and 36-43* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *8/20/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

S-00

DETAILED ACTION

Claims 1-34 and 36-43 are pending in the application.

Priority

Applicant's claim of domestic priority to U.S. Provisional Application Serial No. 60/358,879, filed February 22, 2002, is acknowledged.

Claim Objections

The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

In particular, claim 35 is missing from the listing of claims. Applicants are required to amend the claim numbering to bring into conformance with 37 C.F.R. 1.126.

Claims 8 and 21 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. In

particular, claims 1 and 14, from which claims 8 and 21 respectively depend, recite the polymer having "each subunit consisting of a member of the group selected from L-arginine and physiologically acceptable salts of L-arginine." Claims 8 and 21 fail to further limit these claims, as they recite that the subunits are "selected from L-arginine and physiologically acceptable salts of L-arginine," but do not recite any further limitations on such subunits or on the polymer or composition as a whole. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 27-34 and 36-43 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for *therapeutically caring* for the skin, hair, lips or gums, does not reasonably provide enablement for the prophylactically, i.e. preventively, caring for skin, hair, lips or gums, as recited in claims 27 and 36. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The instant specification fails to provide information that would allow the skilled artisan to fully practice the instant invention without ***undue experimentation***. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Foreman*, 230 USPQ 546 (Board of Appeals 1986) at 547, the court recited eight factors:

(1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art: (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation that is necessary.

(1) *The Nature of the Invention:*

The invention is drawn to a method of prophylactically or therapeutically caring for the skin, hair, lips or gums by applying thereto an enhancing effective amount of a composition.

(2) *Breadth of the Claims:*

The complex nature of the subject matter of this invention is greatly exacerbated by the breadth of the claims. The claimed invention includes the prophylactic (preventive) caring for diverse parts of the body including skin, hair, lips or gums, with any of the numerous compounds encompassed by the composition recited in claim 1 and claim 14. The term "prophylactically" indicates a claim whereby those normally not at risk for developing a skin, hair, lips or gum condition would be prevented from ever developing such a condition with the composition being claimed.

(3) *Guidance of the Specification:*

The guidance of the specification as to "prophylactically" caring for skin, hair, lips or gums is completely lacking. Note that Examples 1-2 on pages 10-14 of the Specification show the enhancement of hair growth and lip contour enhancement using the claimed compositions. Thus, Applicant's specification shows the *therapeutic treatment* or care of skin, lips and hair, but does not teach that such treatment acts prophylactically to prevent any future skin, lip, hair or gum condition. The specification also does not provide any alternative models by which the prevention of conditions and prophylactic care of skin, hair, lips or gums could be assessed.

(4) *Working Examples:*

As discussed in the Guidance of the Specification section above, Applicant has only shown examples for the treatment of skin, hair and lips. Applicant has not shown examples for the complete *prevention* or *prophylactic care* of conditions of the skin, hair, lips or gums.

(5) *State of the Art:*

The state of the art regarding the *therapeutic care* and *treatment* of skin, hair, lips or gums is well developed. However, the state of the art regarding the *prophylactic care* or *prevention* of conditions of the skin, hair, lips or gums, such as for example acne, is underdeveloped (see for example "Optimal Management of Acne to Prevent Scarring and Psychological Sequelae" to Alison M. Layton, Am. J. Clin. Dermatol. 2001; 2(3): 135-141.) Layton describes how acne vulgaris is a common inflammatory dermatosis in which multiple factors are involved, including an increase in sebum production and the proliferation of bacteria (see abstract, in particular.) Layton describes how treatment should be aimed at achieving clearance of acne and prevention of scarring (see page 137, section 4, in particular.) Thus, Layton shows that it is known to clear or therapeutically care for pre-existing acne, but the complete prevention of the acne condition such that it never occurs is not known.

Reasonable guidance with respect to *prophylactically caring for* or *preventing* conditions of the skin, hair, lips or gums relies on quantitative analysis from defined

populations that have been successfully pre-screened and are predisposed to such conditions. This type of data might be derived from widespread genetic analysis, family histories, correlation of genetic and environmental factors, etc. The essential element towards the validation of a preventive therapeutic is the ability to test the therapeutic on subjects monitored in advance of the onset of skin, hair, lips or gum condition, and *link* those results with subsequent histological confirmation of the presence or absence of skin, hair, lip or gum and disorders. This irrefutable link between antecedent drug and subsequent knowledge of the prevention of the condition is the essence of a valid preventive agent. As the correlation among factors contributing to conditions of the skin, hair, lips or gums, such as acne, are not known, the state of the art does not provide a reasonable method of making such a predictive analysis. Further, a preventive administration also must assume that the therapeutic will be safe and tolerable for anyone susceptible to the condition or disease.

(6) *Predictability of the Art*

The invention is directed to *prophylactically* or *therapeutically* caring for skin, hair, lips or gums in *general* by applying an enhancing effective amount of the claimed composition comprising L-arginine subunits. It is well established that "the scope of enablement varies inversely with the degree of unpredictability of the factors involved," and physiological activity is generally considered to be an unpredictable factor. See *in re Fisher*, 427 F.2d 833, 839 (1970.)

It should also be noted that one of ordinary skill in the art would recognize that it is highly unpredictable in regard to what population will experience a skin, hair, lips or gum disorder, such as acne, as discussed in (5) above. In order to administer the agent to the population at large, one would need to consider the therapeutic effects, side effects and especially potential serious toxicity that may be generated by drug-drug interactions as a result of administration of the claimed compounds to a living organism (e.g., an animal.)

(7) ***The Quantity of Experimentation Necessary:***

In order to practice the disclosed invention, one would need to undergo experimentation to test compositions with the claimed compounds to determine whether or not any of them are actually capable of completely preventing skin, hair, lips or gums conditions, and thus prophylactically caring for skin, hair, lips or gums, as the instant specification does not show the complete prevention thereof.

As discussed above, the specification fails to provide sufficient support for determining all individuals susceptible to conditions and/or disorders of the skin, hair, lips and gums to allow one or ordinary skill in the art to administer to a population the L-arginine subunit containing composition of the instant invention for the *prevention* and *prophylactic care* of skin, hair, lips and gums in general. As a result, one of ordinary

skill in the art would be forced to perform an exhaustive search for the population that is susceptible to such disorders resulting therefrom to use the instant invention.

Genentech, 108 F.3d at 1366 states that "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable."

The Examiner suggests deleting the reference to "prophylactically" in claims 27 and 36. For examination purposes, the Examiner is interpreting the claims as drawn to a method of therapeutically caring for the skin, hair, lips or gums.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 14-26 and 36-43 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for reciting that the polymer comprises one or more amino acids other than L-arginine that "are not therapeutically effective," as in claim 14. The claim limitations are indefinite, because it is not clear what is meant by the other amino acids being "not therapeutically effective." Is it intended that the claimed amino acids are incapable of exhibiting any therapeutic effect at all, or merely that the amino acids are not capable of enhancing vasodilation? It is also unclear from the specification as to what is intended by "therapeutically effective." The specification merely states that

glycine is an example of an amino acid that is not therapeutically effective (see page 5, second full paragraph, in particular), but does not teach what therapeutic effect is being meant, or how to determine the other amino acids that might fit the criteria. Accordingly, claim 14 is indefinite because one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Claims 15-26 and 36-43 are rejected as being dependent upon the independent claim 14.

In the interests of compact prosecution and for the purposes of applying prior art, the other amino acid that is "not therapeutically effective" is being interpreted as meaning any amino acid other than L-arginine.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-28, 30, 36-37 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication No. 2002/0009491 to Rothbard et al, published January 24, 2002.

Rothbard et al. teaches providing compositions for enhancing the delivery of drugs and other agents across a biological barrier, such as skin, the composition employing a delivery enhancing transporter, such as a poly-arginine molecule that is between 6 and 50 residues in length (see abstract, in particular.) Rothbard teaches that examples of such delivery enhancing transporters can comprise from 7 to 15 amidino moieties, such as heptamers, octamers, nonamers and the like of arginine (se paragraph 0048, in particular.) Rothbard et al. furthermore teaches that the amino acids can be L amino acids (see paragraph 0055, in particular.) Rothbard et al. teaches that the compositions comprising the polyarginine molecule can comprise a conventional pharmaceutical carrier and can be formulated for topical administration in a suitable format, such as a lotion (see paragraphs 0128 and 0134, in particular), and thus teaches providing a dermatologically acceptable vehicle.

Rothbard et al. does not teach a specific example of composition having a polymer comprising from 7 to 15 subunits of L-arginine in a cosmetically or dermatologically acceptable vehicle. However, as Rothbard et al. teaches that the transport enhancing polymers can comprise from 7 to 15 amidino moieties, such as heptamers, octamers and nonamers of arginine, which may be L-arginines, and furthermore teaches that such transport enhancing agent can be formulated with pharmaceutical carriers for topical administration, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to provide a polymer having a number of arginine subunits within the range recited in claim 1, and

with a dermatologically acceptable vehicle, with the expectation of providing a transport enhancing composition suitable for topical application.

Regarding independent claim 14, Rothbard et al. furthermore teaches that peptides comprising arginine in addition to other amino acid residues can also be used as the delivery-enhancing polymer, and furthermore teaches that the delivery-enhancing transporters of the invention can be flanked by, or interrupted by, one or even more than one non-guanidino/non-amidino subunits (such as glycine, alanine and cysteine), that do not significantly affect the rate of transmembrane transport of the delivery-enhancing compound compositions (see paragraphs 0048 and 0071, in particular.) Accordingly, Rothbard et al. teaches the polymer having contiguous arginine subunits, with a number of subunits that overlaps with the range claimed in claim 14, the polymer being flanked by one amino acid other than L-arginine, in which the L-arginine subunits would be situated at the C-terminus or the N-terminus of the polymer, as recited in claim 14. Rothbard et al. furthermore teaches providing a dermatologically acceptable carrier in combination with delivery-enhancing polymers, as discussed for claim 1 above, and thus the composition recited in claim 14 is also obvious over the teachings of Rothbard et al.

Regarding claims 2-4 and 15-17, Rothbard et al. teaches providing heptamers of arginine (see paragraph 0048, in particular), which is a polymer containing 7 contiguous arginine subunits, and thus meets the limitation of these claims. Regarding claims 5-7

and 18-20, Rothbard et al. teaches that the delivery-enhancing polymer can be formulated as a lotion for application to skin (see paragraph 0134, in particular.) Regarding claims 8-9 and 21-22, Rothbard et al. teaches the subunits are L-arginine (see paragraph 0048, in particular.)

Regarding claims 10-11 and 23-25, Rothbard et al. teaches the topical composition can further comprise skin care actives such as vitamins, antibacterial and analgesics, as well as sunscreen components, among others (see paragraphs 0140-0152, in particular.)

Regarding claims 13 and 26, Rothbard et al. furthermore teaches that small organic molecule agents can be combined with the transporters to facilitate or enhance transport (see paragraph 0076, in particular.) Rothbard et al. teaches that such compounds can include small organic molecules that have poor solubilities in aqueous liquids (see paragraph 0076, in particular), and thus are hydrophobic. Rothbard et al. furthermore teaches that the biologically active agent and delivery enhancing transporter are linked by an ionic association, such as between the charged arginine side chain and a charged group on the biologically active agent (see paragraph 0044 and Figure 1, in particular.) While Rothbard et al. does not specifically exemplify linking the biologically active agent to the side chain of the terminal L-arginine subunit, it is considered that one or ordinary skill in the art at the time the invention was made would have found it obvious to provide such an association, based on the ion pair teachings of

Rothbard et al, with the expectation of providing a suitable transport pair for skin treatment.

Regarding the methods of therapeutically caring for skin, hair, lips or gums by applying an enhancing effective amount of the composition of claims 1 and 14, as recited in claims 27 and 36, it is noted that Rothbard et al. teaches topical compositions comprising the composition for the treatment of skin (see paragraphs 0138-0152, in particular.) As Rothbard et al. teaches that the composition enhances the transport of biologically active agents, it is considered that Rothbard teaches applying an enhancing effective amount of the composition, as recited in the claims.

Regarding claims 28 and 37, Rothbard et al. teaches applying the composition topically, as discussed above. Regarding claims 30 and 39, Rothbard et al. teaches that the composition can comprise retinoids for the treatment of cutaneous aging, and thus teaches alleviating the signs of aging of the skin as recited in the claims.

Claims 29 and 38 are rejected under 35 U.S.C. 103(a) as being obvious over U.S. Patent Application Publication No. 2002/0009491 to Rothbard et al, published January 24, 2002, as applied to claims 1-28, 30, 36-37 and 39 above, and further in view of U.S. Patent No. 4,725,609 to Kull, Jr. et al, issued February 16, 1998.

Rothbard et al. is applied as discussed for claims 1-28, 30 and 36-37 above, and teaches topically applying a composition with a delivery-enhancing transporter comprising the polymer having the L-arginine subunits, as recited in claims 1 and 14. Rothbard et al. teaches that the composition enhances delivery of active agents across a body surface or tissue, such as intact skin or a mucous membrane (see paragraph 0028, in particular.) Rothbard et al. teaches that the biologically active agents transported by the composition can include therapeutic agents comprising any composition that can be used to the benefit of a mammalian species, including small organic molecules, peptides, proteins or polypeptides, and oligosaccharides (see paragraph 0026, in particular.) Rothbard et al. teaches that the delivery enhancement can enhance the depth and extent of delivery of the active agent (see paragraph 0029, in particular.)

Rothbard does not specifically teach applying the composition for the promotion of angiogenesis in hair follicles, as recited in claims 29 and 38.

Kull, Jr. et al. teaches the topical delivery of an agent to promote angiogenesis, re-epithelialization and wound healing (see abstract, in particular.) Kull, Jr. et al. furthermore teaches that the topical formulations can comprise one or more agents to enhance dermal penetration (see column 3, lines 10-35, in particular.) Kull, Jr. et al. demonstrates that application of the topical compositions are capable of epithelial

regeneration, including the regeneration of hair follicle epithelium, on wounded skin areas of animals (see column 5, lines 10-28, in particular.)

Accordingly, one of ordinary skill in the art at the time the invention was made would have found it obvious to provide the angiogenesis enhancing agent of Kull, Jr. et al. in the delivery-enhancing transporter containing composition of Rothbard et al, and topically delivering to promote angiogenesis in hair follicles, because Rothbard et al. teaches that the delivery-enhancing transporter can be used to enhance the delivery of skin benefit active agents to the skin, and Kull, Jr. et al. teaches that angiogenesis enhancing agents can be topically delivered to the skin to promote angiogenesis and wound healing, including of hair follicles, and can also be suitably provided with dermal penetration enhancing agents. Thus, one of ordinary skill in the art at the time the invention was made would have found it obvious to combine and topically apply the angiogenesis enhancing agent of Kull, Jr. et al. with the topical delivery-enhancing transporter composition of Rothbard et al, with the expectation of providing skin care capable of promoting angiogenesis of epithelium including hair follicle epithelium with enhanced penetration of the angiogenesis active agent.

Claims 31 and 40 are rejected under 35 U.S.C. 103(a) as being obvious over U.S. Patent Application Publication No. 2002/0009491 to Rothbard et al, published January 24, 2002, as applied to claims 1-28, 30, 36-37 and 39 above, and further in view of U.S. Patent No. 5,785,978 to Porter et al, issued July 28, 1998.

Rothbard et al. is applied as discussed for claims 1-28, 30 and 36-37 above, and teaches topically applying a composition with a delivery-enhancing transporter comprising the polymer having the L-arginine subunits, as recited in claims 1 and 14. Rothbard et al. teaches that the composition enhances delivery of active agents across a body surface or tissue, such as intact skin or a mucous membrane (see paragraph 0028, in particular.) Rothbard et al. teaches that the biologically active agents transported by the composition can include therapeutic agents comprising any composition that can be used to the benefit of a mammalian species, including small organic molecules, peptides, proteins or polypeptides, and oligosaccharides (see paragraph 0026, in particular.) Rothbard et al. also teaches that the active agents can include vitamins (see paragraph 0095, in particular.) Rothbard et al. teaches that the delivery enhancement can enhance the depth and extent of delivery of the active agent (see paragraph 0029, in particular.)

Rothbard does not specifically teach applying the composition to enhance the appearance of lips, as recited in claims 31 and 40.

Porter et al. teaches skin care compositions to improve the appearance of skin, including the area of the upper lip (see abstract, in particular.) Porter et al. teaches that active agents used to improve such areas of the skin include vitamins (see column 1,

lines44-54, in particular.) Porter et al. furthermore teaches that such compositions can be administered with a permeation enhancer (see column 4, lines 28-40, in particular.)

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the lip appearance enhancing vitamins of Porter et al. into the skin care and delivery-enhanced transporting composition of Rothbard et al, for topical application to enhance the appearance of lips, because Rothbard et al. teaches that the delivery-enhanced transporting composition can be topically applied for skin care and can enhance the penetration of vitamins, and Porter et al. teaches that vitamins can be topically applied to improve the appearance of lips and can be applied with a permeation enhancer. Thus, one of ordinary skill in the art at the time the invention as made would have been motivated to combine and topically apply the lip appearance-enhancing vitamins of Porter et al. with the delivery-enhancing transporting composition of Rothbard et al, with the expectation of applying a composition having enhanced dermal penetration that improves the appearance of lips.

Claims 32 and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication No. 2002/0009491 to Rothbard et al, published January 24, 2002, as applied to claims 1-28, 30, 36-37 and 39 above, and further in view of U.S. Patent No. 5,902,593 to Kent et al, issued May 11, 1999.

Rothbard et al. is applied as discussed for claims 1-28, 30 and 36-37 above, and teaches topically applying a composition with a delivery-enhancing transporter comprising the polymer having the L-arginine subunits, as recited in claims 1 and 14. Rothbard et al. teaches that the composition enhances delivery of active agents across a body surface or tissue, such as intact skin or a mucous membrane (see paragraph 0028, in particular.) Rothbard et al. teaches that the biologically active agents transported by the composition can include therapeutic agents comprising any composition that can be used to the benefit of a mammalian species, including small organic molecules, peptides, proteins or polypeptides, and oligosaccharides (see paragraph 0026, in particular.) Rothbard et al. teaches that the delivery enhancement can enhance the depth and extent of delivery of the active agent (see paragraph 0029, in particular.)

Rothbard does not specifically teach applying the composition to enhance the sensitivity of skin, as recited in claims 32 and 41.

Kent et al. teaches a topically applied composition comprising an active ingredient, benzalkonium chloride, that increases tissue sensation (see abstract and column 1, lines 25-40, in particular.) Kent et al. teaches that the topical medicament is applied to sensitive tissue areas to produce increased sensitivity to physical contact (see column 1, lines 5-10, in particular.)

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the skin sensitivity enhancing active agent of Kent et al. into the skin care and delivery-enhanced transporting composition of Rothbard et al, for topical application to enhance the sensitivity of skin, because Rothbard et al. teaches that the delivery-enhanced transporting composition can be topically applied for skin care and to provide skin benefits by enhancing the penetration of active agents, and Kent et al. teaches that active agents can be topically applied to improve the sensitivity of skin. Thus, one of ordinary skill in the art at the time the invention as made would have been motivated to combine and topically apply the skin sensitivity-enhancing agents of Kent et al. with the delivery-enhancing transporting composition of Rothbard et al, with the expectation of applying a composition having enhanced dermal penetration that improves the sensitivity of skin.

Claims 33 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication No. 2002/0009491 to Rothbard et al, published January 24, 2002, as applied to claims 1-28, 30, 36-37 and 39 above, and further in view of U.S. Patent No. 5,637,316 to Ribier et al, issued June 10, 1997.

Rothbard et al. is applied as discussed for claims 1-28, 30 and 36-37 above, and teaches topically applying a composition with a delivery-enhancing transporter comprising the polymer having the L-arginine subunits, as recited in claims 1 and 14. Rothbard et al. teaches that the composition enhances delivery of active agents across

a body surface or tissue, such as intact skin or a mucous membrane (see paragraph 0028, in particular.) Rothbard et al. teaches that the biologically active agents transported by the composition can include therapeutic agents comprising any composition that can be used to the benefit of a mammalian species, including small organic molecules, peptides, proteins or polypeptides, and oligosaccharides (see paragraph 0026, in particular.) Rothbard et al. teaches that the delivery enhancement can enhance the depth and extent of delivery of the active agent (see paragraph 0029, in particular.)

Rothbard does not specifically teach applying the composition for the stabilization or remodeling of fat, as recited in claims 33 and 42.

Ribier et al. teaches a slimming composition for topical treatment comprising a first dispersion capable of penetration into deep layers of the skin and containing at least one active agent chosen from lipolytic and firming agents (see abstract, in particular), and thus teaches providing an active agent for the stabilization or remodeling of fat. Ribier et al. teaches that it is desirable to be able to deliver such slimming agents to deep layers of the skin (see column 2, lines 46-54, in particular.) Ribier et al. teaches that active slimming agents for such deep-down action can include caffeine, nicotinic acid derivatives, and gingko biloba, among others (see column 6, line 32, through column 7, line 6, in particular.)

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the slimming active agents of Ribier et al. into the skin care and delivery-enhanced transporting composition of Rothbard et al, for topical application to stabilize or remodel fat, because Rothbard et al. teaches that the delivery-enhanced transporting composition can be topically applied for therapeutic skin care and can enhance the penetration of active agents, and Ribier et al. teaches that slimming active agents can be topically applied to combat plumpness and firm (see abstract and column 7, lines 45-55, in particular) and are desirably applied with a composition that is capable of delivering the slimming agents to deep layers of the skin. Thus, one of ordinary skill in the art at the time the invention as made would have been motivated to combine and topically apply the slimming active agents of Ribier et al. with the delivery-enhancing transporting composition of Rothbard et al, with the expectation of applying a composition having penetration into deep skin layers that combats plumpness and firms to provide stabilization and remodeling of fat.

Claims 34 and 43 are rejected under 35 U.S.C 103(a) as being unpatentable over U.S. Patent Application Publication No. 2002/0009491 to Rothbard et al, published January 24, 2002, as applied to claims 1-28, 30, 36-37 and 39 above, and further in view of U.S. Patent No. 4,933,172 to Clark, Jr. et al, issued June 12, 1990.

Rothbard et al. is applied as discussed for claims 1-28, 30 and 36-37 above, and teaches topically applying a composition with a delivery-enhancing transporter

comprising the polymer having the L-arginine subunits, as recited in claims 1 and 14. Rothbard et al. teaches that the composition enhances delivery of active agents across a body surface or tissue, such as intact skin or a mucous membrane (see paragraph 0028, in particular.) Rothbard et al. teaches that the biologically active agents transported by the composition can include therapeutic agents comprising any composition that can be used to the benefit of a mammalian species, including small organic molecules, peptides, proteins or polypeptides, and oligosaccharides (see paragraph 0026, in particular.) Rothbard et al. teaches that the delivery enhancement can enhance the depth and extent of delivery of the active agent (see paragraph 0029, in particular.)

Rothbard does not specifically teach applying the composition for the treatment of gum regression, as recited in claims 34 and 43.

Clark, Jr. et al. teaches methods for treating destructive periodontal disease comprising applying a therapeutic agent directly to gingival tissue, such as gums (see abstract and column 2, lines 47-62, in particular.) Clark, Jr. et al. teaches that therapeutic active agents are capable of inhibiting the conversion of gingivitis to periodontitis and treating gingivitis (see column 1, lines 5-55, in particular), which are conditions associated with the inflammation of gums and gum recession.

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the periodontal disease treating active agent of Clark, Jr. et al. into the skin care and delivery-enhanced transporting composition of Rothbard et al, for topical application to treat gum regression, because Rothbard et al. teaches that the delivery-enhanced transporting composition can be topically applied to tissue including skin and mucous membranes to provide benefits to the tissue by enhancing the penetration of active agents, and Clark, Jr. et al. teaches that active agents can be topically applied to gum tissue to treat periodontal disease, and thus treat gum regression. Thus, one of ordinary skill in the art at the time the invention as made would have been motivated to combine and topically apply the periodontal disease treating agents of Clark, Jr. et al. with the delivery-enhancing transporting composition of Rothbard et al, with the expectation of applying a composition having enhanced dermal penetration that treats periodontal disease.

Conclusion

No claims are allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. In particular, U.S. Patent No. 5,891,459 to Cooke et al, issued April 6, 1999, teaches formulations for the enhancement of vascular function by modulation of endogenous nitric oxide production or activity (see abstract, in particular.)

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Abigail M. Cotton whose telephone number is (571) 272-8779. The examiner can normally be reached on 8:30-5:00, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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AMC

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER